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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,610	03/13/2001	John J. Coogan JR.	T3I-001	9302

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,610

Applicant(s)

COOGAN ET AL.

Examiner

Susan Hanley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

PD

DETAILED ACTION

Applicant's amendment filed May 20, 2005 has been entered.

Claims 1-9 and 16-21 are pending.

Information Disclosure Statement

Applicant states that copies of the non-patent literature were submitted to the PTO with the initial IDS submission and have been misplaced by the Office. Applicant submits that their submission fully complies with 37 CFR 56.

Reference that are not present in the IDS, for what ever reason, cannot be reviewed by the Examiner. Applicant can perfect the IDS submission by resubmitting the non-patent references. There are no fees associated with the resubmission of the non-patent documents.

Response to Arguments

Applicant's arguments with respect to claims 1-6 and 16-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morgan et al. (US 5,834,784).

Morgan et al. disclose an apparatus with an excimer gas filled ultraviolet generating lamp for sterilizing liquids to kill bacteria (col. 1, lines 6-11). The lamp is powered by AC voltage. A cooling liquid is pumped between two quartz cylinders that hold said gas. The gas emits light outwardly to the treatment area (Figure 1), as in instant claim 19. The cooling liquid is pumped through the volume inside quartz cylinders. The gas enclosure is enclosed within, but spaced from a metal housing which is fluid-

Art Unit: 1651

tight, as required by instant claim 16a. The treated liquid is separate from the cooling liquid because it is pumped around the cylinders that hold the gas (abstract). The excimer gas can be XeBr, but can be changed as desired depending on the wavelength that is needed. XeBr emits light at 320 nm, as required by . Therefore it is monochromatic since it emits light of a single wavelength. The surface geometry is cylindrical to accommodate the flow of a liquid that is in need of sterilization, as required by instant claims 15a and 18.

Morgan et al. do not teach that the disclosed sterilizing apparatus can sterilize complex fluids, as claimed in the preamble. However, this claimed effect does not make the instant claims patentable over the prior art because the prior art sterilizing apparatus meets the claimed structural requirements. Therefore, it is inherently capable of sterilizing complex fluids.

MPEP 2112.02: PROCESS CLAIMS - PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231USPQ 136 (Fed. Cir. 1986) See also In re Best, 562F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993

Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-6, 8, 9 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holbert et al. (US 5,730,934) or Sizer (US 5,843,374) in view of Morgan et al. (US 5,834,784).

Art Unit: 1651

Holbert teaches an apparatus for sterilizing of packaging material wherein the apparatus comprises an excimer lamp that emits monochromatic light and said lamp has an aperture through which a cooling material may flow. Holbert teaches that the cooling material can be the desired contents for the container (col. 7, lines 5-10 and claims 18-23). Sizer teaches this element at col. 7, lines 47-27. Holbert teaches that flowing food products comprise juices and milk (col. 1, lines 15-17). Sizer teaches this element at col. 1, lines 20. Milk meets the limitation for a complex fluid because it contains heat-sensitive materials (i.e. proteins). Thus, milk is a complex fluid that contacts a monochromatic light source as it flows into a carton. During this process, *both the milk and the carton are sterilized* because the milk is exposed to the light source. A bound volume of photon-producing gas is encased within a fluid-tight housing. Holbert teaches that the UV source is a photon-producing gas such as XeCl that is contained in a cylindrical shell. Figure 1 shows a cross section wherein the cooling fluid 28 flows through an aperture formed by a 3-dimensional ring (which corresponds to the shaded area bound by inner ring 26 and outer ring 24) that encloses the excimer gas 22. Sizer also teaches that the UV source is a photon-producing gas such as XeCl that is contained in a U-shaped shell. Figure 1 shows a cross section wherein the cooling fluid flows on a pathway 38 on the exterior of the lamp. The U-shaped shell encloses the excimer gas 22. Thus, the cooling fluid, which may be milk, flows through the pathways indicated by Holbert and Sizer and is in thermal contact with a sealed volume that contains the light emitting gas. The excimer gas emits light over the entire surface of said cylindrical shell, thus meeting the limitation of a "light emitting surface geometry."

Neither Holbert et al. nor Sizer et al. disclose that the apparatus that sterilizes the complex fluid comprises a cooling liquid that is in thermal communication with the light emitting surface that is distance from the complex fluid.

The disclosure by Morgan et al. is discussed *supra*.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the UV light source taught Morgan et al. for the for the light source taught by

Art Unit: 1651

Sizer et al. or Holbert et al. for the sterilization of complex fluids such as milk by irradiation. The ordinary artisan would have been motivated to do so because both apparatus are *directed to the same purpose*, sterilizing. The sterilization apparatus taught by Morgan et al. is nearly identical to that of Sizer et al. and Holbert et al. The ordinary artisan would have recognized that the separation of the cooling liquid from the complex fluid would be convenient since the cooling liquid could be recirculated and used multiple times without removal from the apparatus. This set up is analogous to a distillation which is a common method for cooling liquids. The ordinary artisan would have had a reasonable expectation that the apparatus of Morgan et al. could perform the sterilization of complex liquids because it emits the desired wavelength from an excimer gas and has a geometry that is appropriate to accommodate any liquid.

Claims 1-6, 8, 9 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson (US 5,433,738) in view of Morgan et al. (US 5,834,784).

Stinson teaches that a cell suspension can be treated by positioning it adjacent to a substantially transparent portion of an out wall surrounding a light source (col. 3, lines 12-30 of Stinson). A cell suspension comprises proteins and DNA which are heat sensitive. Therefore the disclosed cell suspension meets the limitation of a complex fluid as required by instant claim 1. Said cell suspension can comprise a blood product or an injectable solution or both, as required by instant claim 3 (col. 11, lines 16-25 of Stinson). The light source emits UV light having a wavelength that falls between 280 and 320 which falls within the claimed range of instant claim 4. Said ranges constitutes monochromatic light as required by instant claim 2 (col. 6, lines 48-60 of Stinson). The light is positioned in a sealed cylinder made of fused silicate glass, as required by claims 1 and 6 (col. 6, lines 35-40 of Stinson). Stinson teaches that it is necessary to ventilate the lamp to maintain the lamp temperature which inherently prevents the heat generated by the lamp from damaging a heat sensitive component of the blood being treated. Air is used as a coolant by contacting it with the lamp (col. 8, lines 41-65 of Stinson).

Art Unit: 1651

Stinson does not teach treating the cell suspension which can comprise blood with UV light generated by an excimer source or a cooling fluid in thermal communication with the UV light source but separate from the complex fluid.

The disclosure by Morgan et al. is discussed *supra*.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the UV light source taught Morgan et al. for the for the light source taught by Stinson for the sterilization of a cell suspension which can comprise blood by irradiation. The ordinary artisan would have been motivated to do so because both apparatus are directed to the same purpose, the sterilizing of liquids. The ordinary artisan would have recognized that the employment of a liquid to cool the lamp is more effect than the use of air for said purpose. The ordinary artisan would have had a reasonable expectation that the apparatus of Morgan wt al. could perform the sterilization method of Stinson because it emits the desired wavelength from an excimer gas and has a geometry that is appropriate to accommodate any liquid.

Claims 1, 2, 5-9 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuhl (US 3,986,513) in view of Stinson (US 5,433,738), Hartman (US 6,447,537) and Morgan et al. (US 5,834,784).

Stuhl discloses an apparatus and method of treating skin on a body area of a patient, especially for psoriasis, comprising a base on which a patient can rest and radiation units positioned adjacent to said patient. The disclosure of skin meets the limitation of claims 1 and 16 that require a complex fluid because cells comprise fluid in which heat sensitive components such as proteins and nucleic acids reside. The treatment for psoriasis can include the administration of a photoactive compound such as methoxysalen to a patient, thus meeting the limitation of claim 7. The treatment comprises irradiation of the body area of the patient where psoriasis is evident by means of UV lamps having a wavelength between about 320 and 400 nm (col. 2, lines 555). Stuhl further discloses that it is necessary to remove heat

Art Unit: 1651

generated by the lamps. Stuhl teaches cooling the lamps by circulating air around said lamps. Said circulated air can be provided by a fan (col. 5, lines 56-66 of Stuhl).

Stuhl does not disclose irradiation with monochromatic light, the use of UV light generated by an excimer source or a cooling fluid in thermal communication with the UV light source but separate from the complex fluid.

The disclosures by Stinson and Morgan et al. are discussed *supra*.

Hartman discloses that the treatment of psoriasis is more effective by directing UV light of a single wavelength to the affected body area (col. 3, lines 48-56). Hartman teaches directing monochromatic light having a wavelength of 311 nm to an affected area (claim 13 of Hartman).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating psoriasis disclosed by Stuhl by using a monochromatic light of 311 nm as taught by Hartman because Hartman has shown that using monochromatic light around 311 nm is a more effective treatment for psoriasis.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the UV light source taught by Stuhl et al. for the for the light source taught by Morgan et al. for the treatment of psoriasis by irradiation. The combined disclosures of Stuhl and Hartman requires that a UV-generating light having a wavelength of 311 nm is positioned near the body area of a person affected by psoriasis such that said body area is irradiated by said light source. Stuhl also teaches that it is important to cool the light source by circulating air around it. The ordinary artisan would have been motivated to employ the excimer source taught by Morgan et al. in the system of Stuhl and Hartman because the excimer light source of Morgan produces light in the range required by the combined disclosures of Stuhl and Hartman and provides a surface area of generated light that would be suitable to irradiate an area of a body. Furthermore, the light source taught by Morgan et al. is cooled which is also required by the system of Stuhl. The ordinary artisan would have realized that the fluid cooling method of Morgan et al. is more efficient than blowing air by a fan in the general direction of the

Art Unit: 1651

UV lamps. The ordinary artisan would have had a reasonable expectation that the light source taught by Morgan et al. would successfully irradiate a body part to treat psoriasis because said source generates light at a suitable wavelength for such a purpose and said source is suitably cooled, as required by the combined disclosure of Stuhl and Hartman.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

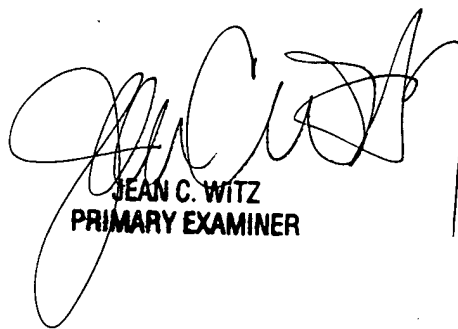
Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
1651



JEAN C. WITZ
PRIMARY EXAMINER